US009636223B2

(12) **United States Patent**
Khalil et al.

(10) **Patent No.: US 9,636,223 B2**
(45) **Date of Patent: May 2, 2017**

(54) **SYSTEMS AND METHODS FOR PLACING A COAPTING MEMBER BETWEEN VALVULAR LEAFLETS**

(71) Applicant: **Edwards Lifesciences Corporation**, Irvine, CA (US)

(72) Inventors: **Vivian Khalil**, Newport Beach, CA (US); **Erin Spinner**, Newport Beach, CA (US); **Neil Zimmerman**, Newport Beach, CA (US); **Alexander Siegel**, Costa Mesa, CA (US); **Son V. Nguyen**, Irvine, CA (US)

(73) Assignee: **Edwards Lifesciences Corporation**, Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 603 days.

(21) Appl. No.: **13/895,611**

(22) Filed: **May 16, 2013**

(65) **Prior Publication Data**

US 2013/0325110 A1 Dec. 5, 2013

Related U.S. Application Data

(60) Provisional application No. 61/647,973, filed on May 16, 2012, provisional application No. 61/734,728, filed on Dec. 7, 2012.

(51) **Int. Cl.**
A61F 2/24 (2006.01)

(52) **U.S. Cl.**
CPC ***A61F 2/2427*** (2013.01); ***A61F 2/246*** (2013.01); ***A61F 2/2454*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61F 2/24; A61F 2/2427; A61F 2/2436; A61F 2/246; A61F 2/2466; A61F 2/2418; A61F 2/2442; A61F 2/2463
(Continued)

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,735,842 A * 4/1998 Krueger A61F 2/2427 606/1
6,629,534 B1 10/2003 St. Goar et al.
(Continued)

OTHER PUBLICATIONS

International Search Report, Aug. 14, 2013.
(Continued)

Primary Examiner — Kathleen Holwerda
(74) *Attorney, Agent, or Firm* — Guy Cumberbatch, Esq.

(57) **ABSTRACT**

The present invention relates to devices and methods for improving the function of a defective heart valve, and particularly for reducing regurgitation through an atrioventricular heart valve—i.e., the mitral valve and the tricuspid valve. For a tricuspid repair, the device includes an anchor deployed in the tissue of the right ventricle, in an orifice opening to the right atrium, or anchored to the tricuspid valve. A flexible anchor rail connects to the anchor and a coaptation element on a catheter rides over the anchor rail. The catheter attaches to the proximal end of the coaptation element, and a locking mechanism fixes the position of the coaptation element relative to the anchor rail. Finally, there is a proximal anchoring feature to fix the proximal end of the coaptation catheter subcutaneously adjacent the subclavian vein. The coaptation element includes an inert covering and helps reduce regurgitation through contact with the valve leaflets.

23 Claims, 23 Drawing Sheets